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In re: Odidi et al.
Serial No. 09/845,497
Docket No. 9577-25

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Remarks/Arguments

Claims 1, 6-9, 11, 15-17 and 21-34 remain in this application. Claim 17 has been amended to correct a clerical error.

Claim Rejections- Detailed Action, II

Claims 17, 21, 23, 30 and 33 are continued to be rejected under 35 U.S.C. §103(a) as being unpatentable over Japanese Patent No. 03197421 to Hirashima (hereinafter "Hirashima"). The Office Action asserts that the amount of both PEG and polymer taught in Hirashima and the instant invention only differs by 10% and for this reason it is necessary for the Applicant to show the criticality of these small differences. The Office Action further asserts that both Hirashima and the instant invention employ the same polymers (e.g. cellulose esters) and that the cellulose ester taught in Hirashima which is semi-permeable, would have the same property of being semi-permeable in the instant invention. Applicant respectfully disagrees.

With respect to independent Claims 17, 23 and 33, these claims are directed to an extended release pharmaceutical active formulation comprising an encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 to less than 50% by weight of polymer and 0.5%-30% by weight PEG or 0.5%-30% by weight plasticizer comprising polyethylene glycol in the coat. Although the Examiner asserts that both PEG and polymer taught in Hirashima and the instant invention only differs by 10%, it is respectfully submitted that Hirashima does not teach or suggest the specific combination of about 5 to less than 50% by weight of a polymer with 0.5%-30% by weight PEG that would provide the encasement coat of the claimed invention, that is, an encasement coat being non-permeable and soluble in a pH of above about 5.0. To establish *prima facie* obviousness of a rejected claim, the applied art of record must teach or suggest each and every feature of a rejected claim. See M.P.E.P. §2143.03. Hirashima does not teach or suggest a coat having the properties of the coat of the claimed invention or the specific percentage(s) ranges of components of the claimed invention.

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The Office Action further asserts that both Hirashima and the instant invention employ the same polymers (e.g. cellulose esters) and that the cellulose ester taught in Hirashima which is semi-permeable, would have the same property of being semi-permeable in the instant invention. The polymer taught by Hirashima is ethyl cellulose not a cellulose ester. As a result, the coat of Hirashima would be permeable. The polyethylene glycol of the coat of Hirashima would dissolve in solution producing porous channels in the coat, while maintaining its' integrity even after the active had leached out. The coat of Hirashima would not be soluble at any pH. In contrast, the coat of the claimed invention is non-permeable (not permeable) and soluble in a pH of above about 5.0.

For these reasons, it is respectfully submitted that independent Claims 17, 23 and 33 are patentable over Hirashima and consequently, Claims 21 and 30, which are dependent, or ultimately dependent, from Claim 17, are also patentable over Hirashima.

Claim Rejections- 35 U.S.C. §112, first paragraph

Claims 1, 6-9, 15-17, and 21-34 are rejected under 35 USC 112, first paragraph. The Office Action asserts that there is no reasonable enablement for the polymeric film being cellulose esters. The Office Action notes, for example, that the invention requires that the polymeric film be non-permeable and that the instant invention can use cellulose esters to formulate the non-permeable film; however, U.S. Patents Nos. 6,099,859 to Cheng et al. (hereinafter "Cheng") and 6,106,864 to Dolan et al. (hereinafter "Dolan") disclose that cellulose esters are semi-permeable rather than non-permeable.

The references cited by the Office Action teach the use of non-enteric cellulose esters, such as cellulose acetate, and other non-dissolving polymers. In Dolan, cellulose acetate is described as being both impermeable and semi-permeable (see column 3, lines 11-22 and 32-27). The cellulose esters chosen for the instant invention must be combined in the percentages claimed, and must provide the encasement coat with the features instantly claimed; be non-permeable and soluble in a pH of above about 5.0. Therefore, one skilled in the art would know to choose cellulose esters, such as enteric cellulose esters, that would yield the specifically

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claimed properties of the encasement coat. Therefore, cellulose esters are enabled in the context of the claimed invention.

Claims 1, 6-9, 11, 15-17, and 21-34 are rejected under 35 USC 112, first paragraph as failing to comply with the written description. The Office Action asserts that the specification does not explain what is mean by the phrase "a non-permeable polymeric film". This particular phrase is not used in these claims. It is respectfully submitted that the terms "non-permeable" and "polymeric film" are used in these claims. It is submitted that one skilled in the art would clearly understand the term "non-permeable" as not being permeable and the term "polymeric film" in the context of the claimed invention would also be clearly understood by one skilled in the art. These claims, therefore, comply with the written description requirement.

Claim Rejections- 35 U.S.C. §103(a)

Claims 1, 6-9, 11, 15-17, and 21-34 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,106,864 to Dolan et al. (hereinafter "Dolan") and U.S. Patent No. 5,800,422 to Dong et al. (hereinafter "Dong") and U.S. Patent No. 6,099,859 to Cheng (hereinafter "Cheng").

The Office Action asserts that Dolan teaches oral dosage forms of actives and teaches that a matrix comprising the active can be coated with an impermeable coating (see column 2, lines 53-57; see column 3, lines 1-7). It is submitted, however, that Dolan actually teaches that the impermeable coating is provided with an aperture (see column 3, lines 1-7).

The Office Action also asserts that Dolan teaches that ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers (see column 3, lines 7-38). (Please note that ethyl cellulose is not a cellulose ester). Dolan's coat is either impermeable, as noted in (c) at column 2, lines 42-44 and column 3, lines 11-21, or the coat can have low aqueous solubility (e.g. water soluble at pH >5), as noted in (d) at column 2, lines 46-47, and column 3, lines 22-30. As discussed above with respect to 35 USC 112, first paragraph, Dolan teaches the use of non-enteric cellulose esters, such as cellulose acetate, and

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other non-dissolving polymers in conjunction with an impermeable coat, as noted in (c) at column 3, lines 11-21, and with a semi-permeable coat, as noted in (e) at column 3, lines 32-37. Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0.

The Office Action further asserts that Dolan does not specifically teach the percentage ranges of components of the polymeric coating of the instant invention and in the absence of unexpected results showing the significance of the instantly claimed range of polymer, the ideal amount of polymer used in Dolan may fall within the instant range of polymer amount being claimed. As discussed above, Dolan does not teach or suggest an encasement coat, as a whole, being both non-permeable and soluble in a pH of above about 5.0. In addition, in Applicant's Amendment and Response dated March 8, 2004, a Declaration was submitted where it was shown that Cheng teaches the use of non-enteric cellulose esters and other non-dissolving polymers and, as a result, Cheng's formulation provides a different release profile of the drug as is shown in the declaration by co-inventors Dr. Amina Odidi and Dr. Isa Odidi. The declaration provided dissolution data between a model drug using the presently claimed formulation versus that taught by Cheng. As was seen in the graph, the release of the drug using the presently claimed formulation was initially much more rapid which peaks and then provides a consistent level of release over several hours. In contrast, the Cheng formulation exhibits an initial slow dissolution which does not peak for several hours. Therefore, the specific percentage ranges instantly claimed provide unexpected results in comparison to Cheng and hence, in comparison to Dolan since similar coatings are used in Dolan (e.g. the use of non-enteric cellulose esters and other non-dissolving polymers).

For these reasons, it is respectfully submitted that Claims 1, 6-9, 11, 15-17, and 21-34 are patentable over Dolan, Dong and Cheng. Dong and Cheng do not overcome the above-noted deficiencies of Dolan.

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Conclusion

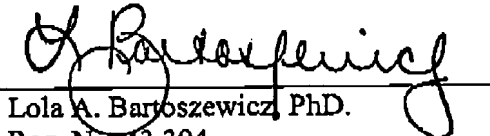
In view of the foregoing, reconsideration of the application, withdrawal of the outstanding rejections, allowance of all of the pending claims 1, 6-9, 11, 15-17, 21-34, and the issuance of a Notice of Allowability are respectfully solicited.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fees for such an extension, together with any additional fees that may be due with respect to this paper, may be charged to Sim & McBurney's Account No. 192253, referencing docket number 9577-25 LAB.

Respectfully submitted,

SIM & MCBURNEY

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